



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/661,361

09/12/2003

David A. Mackiewicz

ENDOS 64949 (4164P)

6762

24201 7590 10/14/2008
FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,361	Applicant(s) MACKIEWICZ ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-18,21,32 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-18,21,32 and 42-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 51 and 52 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 51 and 52 are duplicate claims of claims 48 and 49.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6, 7 and 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the mounting region can be larger than the opening or have an angle which is larger than the opening since final product shows that the mounting region fits within the opening. Therefore the final apparatus has a mounting region and an opening that are similar in size.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 42, 43, 46-52 is rejected under 35 U.S.C. 102(b) as being anticipated by Frantzen (US 5,741,327).

4. Frantzen discloses an implantable medical device comprising a structural body having a certain level of radiopacity (nitinol) and a plurality holder integrally formed therein (For example Fig. 11, 64, 67). The device comprises a plurality of radiopaque markers (96) attachable within the marker holder. The marker holder includes a pair of projecting fingers, which define an opening (62) having a first shape. The radiopaque marker (94) includes a mounting region (96) having substantially the same shape as the opening (Fig. 9; C10:L1-6). The mounting region includes side edges that are adapted to (capable of) contacting the projecting fingers to cause the fingers to move outwards to move the opening into a second expanded shape (when the marker (knob 94) is inserted through (neck 92) of marker holder it is capable of causing the fingers to move outwards since the size of the marker is clearly larger then the opening at the neck). The marker holder applies a force on the mounting region of the marker (C10:L1-6 states that the parts are snapped securely necessarily indicating that a force is being applied. Additionally when the marker is placed in the neck a force is applied.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3731

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (USPN 5,741,327) in view of Stenzel (US 2002/0111671).

5. Frantzen discloses a stent comprising a structural body having a certain level of radiopacity (nitinol) and at least one marker holder integrally formed therein (For example Fig. 11, 64, 67). The device comprises a radiopaque marker (96) attachable within the marker holder. The marker holder includes a pair of projecting fingers, which define an opening (62). The radiopaque marker (94) includes a mounting region (96) that fits within the opening defined by the fingers. The projecting fingers apply a force on the mounting region which holds the marker on the marker holder. (C10:L1-6; In order for the knob (mounting region) to snap securely into the rounded space (opening), the rounded space (opening) necessarily applies force on the knob (mounting region). The projecting fingers are connected at a notched region (for example Fig. 7, 68), which allows the projecting fingers to move laterally to accept the radiopaque marker. The marker is attached to the fingers by a heat weld (Col 7, L64).

6. Frantzen does not disclose that the opening and the radiopaque marker are V-shaped. However, Stenzel disclose locking members that take on many forms including bulbous and arrow shaped (Fig 2, 4, 6). It would have been obvious to one having ordinary skill in the art at the time of the invention to alter the shape of the radiopaque markers and corresponding space to be V-shaped, since it is a design choice that is

Art Unit: 3731

know in the art. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results. Furthermore, such a modification would have involved a mere change in the shape of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 6, 7, 32, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view of Stenzel as applied above, and further evidenced by Lee (US 5,741,327).

7. Frantzen modified by Stenzel does not disclose that the marker has an angle that is larger than the angle of the opening or that the mounting region is larger than the opening. Frantzen does disclose that markers snap securely into the rounded space, but does not explicitly state that a difference in size between the two parts is what allows the parts to snap into space. Additionally, Lee discloses that several equivalent methods of securing radiopaque markers, including by adhesive, by swaging, by crimping, by soldering, or by spring-action tension fit (C4:L6-10). To achieve a "spring action tension fit" would necessarily require the marker holder to apply force and be biased toward the direction that the force is applied and thus have a smaller opening than the shape of the marker. It would have merely required common sense to determine that the openings would necessarily need to be smaller than the size of the markers in order to apply spring action tension fit to hold the markers in the marker holders.

Claims 8-15, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view in view of Stenzel and further in view of Duerig et al (USPN 6,503,271).

8. Frantzen modified by Stenzel discloses the device substantially as claimed as stated above except for the limitation that the radiopaque marker is made from a nickel-titanium alloy including a ternary element. However, Duerig discloses a stent with radiopaque markers that are made from a nickel-titanium alloy with a ternary element that is platinum (Col 10, lines 15-23). Duerig further discloses that use of a micro-alloy is advantageous to overcome the challenge of galvanic corrosion (Col 4, lines 22-24). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a micro alloy into the invention of Frantzen modified by Lee in order to provide an enhanced material that prevents galvanic corrosion.

9. Regarding claim 10, Frantzen modified by Stenzel and Duerig discloses the claimed invention except for the atomic percent of platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide platinum in the percentage of between and including 2.5% and 15%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view of Stenzel in view of Duerig et al (USPN 6,503,271) and further evidenced by Lee (US 5,741,327).

10. Frantzen modified by Stenzel does not disclose that the marker has an angle that is larger than the angle of the opening or that the mounting region is larger than the opening. Frantzen does disclose that markers snap securely into the rounded space, but does not explicitly state that a difference in size between the two parts is what allows the parts to snap into space. Additionally, Lee discloses that several equivalent methods of securing radiopaque markers, including by adhesive, by swaging, by crimping, by soldering, or by spring-action tension fit (C4:L6-10). To achieve a "spring action tension fit" would necessarily require the marker holder to apply force and be biased toward the direction that the force is applied and thus have a smaller opening than the shape of the marker. It would have merely required common sense to determine that the openings would necessarily need to be smaller than the size of the markers in order to apply spring action tension fit to hold the markers in the marker holders.

Response to Arguments

11. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731